Serving Size Proposed Rule

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Nutrition Labeling and Education Act of 1990 (NLEA)

- Gave FDA the explicit authority to provide for nutrition labeling on packaged foods based on a serving size

- an amount customarily consumed and expressed in a common household measure that is appropriate to the food

Reference Amounts Customarily Consumed (RACCs) and Serving Sizes

- In 1993 FDA established RACCs based on national consumption data
- Provided manufacturers with rules to determine serving size of their product from the appropriate RACC

Advance Notice of Proposed Rulemaking (ANPRM)

- 2005 – FDA issued a ANPRM that requested comment:
  - Single-Serving Containers
  - Dual Column Labeling
  - Updating the RACCs

- Comments to the ANPRM were considered during this proposed rulemaking

Key Proposed Changes

- Amend the definition of a single-serving container
- Require dual-column labeling for certain packages
- Update, modify and establish reference amounts customarily consumed

Current Definition of a Single-Serving Container

- A product that is packaged and sold individually and contains less than 200% of the Reference Amount Customarily Consumed (RACC)
- A package that can reasonably be consumed in a single-eating occasion

Current Definition of a Single-Serving Container - Exceptions

- If a product has a large RACC (i.e., 100 g or 100 mL) and contains between 150 and 200% of the RACC, it may be labeled as one or two servings

Current Definition of a Single-Serving Container – Exceptions

- Products packaged and sold individually and containing 200% or more of the RACC can be labeled as a single-serving container if the package can reasonably be consumed at a single-eating occasion

Large RACC Products Labeled as 1 or 2 Servings

- In the 1993 final rule on serving size FDA determined that the average variability[1] in the amount consumed for foods with a large RACC is about two-thirds of the average variability for foods with a smaller RACC

[1]Average variability is defined as the standard deviation as a percent of the mean

Large RACC Products Labeled as 1 or 2 Servings (cont.)

- This means an individual is more likely to consume twice the RACC of a product with a smaller RACC than twice the RACC of a product with a large RACC

Rationale for Proposed Amendment

- The agency examined the correlation between the consumption variation[1] and the RACCs for all products regardless of the RACC

[1]The consumption variation is defined as the standard deviation of the median consumption amount divided by the median consumption and expressed as the percent of the median consumption amount.

Rationale for Proposed Amendment (cont.)

- Results show a low correlation between the RACCs and the consumption variation for all products

  - An individual is just as likely to consume about twice the RACC of a product with a smaller RACC as it is that he or she would consume about twice the RACC of a product with a large RACC

Proposal for a Single-Serving Container

- A product that is packaged and sold individually and that contains less than 200% of the RACC must be labeled as a single-serving container regardless of the RACC
- A package that can reasonably be consumed in a single-eating occasion

Proposal for a Single-Serving Container (cont.)

- Eliminate the provision that packaged foods sold individually and containing 200% or more of the RACC may be labeled as a single-serving container if the package can reasonably be consumed at a single-eating occasion

Dual-Column Labeling (DCL)

- Dual-column labeling refers to presenting two columns of nutrition information in the NFL
  - Manufacturers can now voluntarily provide dual-column labeling by listing nutrition information for two or more forms of the same food (e.g., “purchased” and “prepared”)
  - Nutrition information can also be presented for foods commonly combined with other ingredients or otherwise prepared before eating (e.g., cereal and milk)

Consumer Studies on DCL

- FDA conducted consumer research to help increase understanding of whether modifications to the label format may help consumers use the label[1]

[1]Lando, A. M., S. C. Lo. "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Food Choices," Journal of the Academy of Nutrition and Dietetics, 113:241-50, 2013

Consumer Studies on DCL (cont.)

- The study compared participants' ability to perform tasks such as evaluating product healthfulness and calculating the number of calories and other nutrients per serving and per container
- Compared participants' overall attitudes toward these labels
  - Using the current label versus modified versions of the current label

Consumer Studies on DCL (cont.)

- Results showed that dual-column labels resulted in more participants correctly identifying the number of calories per container and the amount of other nutrients per container and per serving, among other findings

Consumer Studies on DCL (cont.)

- In another study, participants were given a snack food product with either a single-column nutrition label (per serving) or a dual-column nutrition label (per serving and per container)[1]

[1]Antonuk, B., L. Block. "The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food," Journal of Nutrition Education and Behavior, 38:365-70, 2006.

Consumer Studies on DCL (cont.)

- Findings suggested that dual-column labeling led consumers who were not dieting to reduce the amount of food they consumed
- Authors speculated that a dual-column label works as a contextual cue that raises awareness of the amount of food consumed in a package for certain consumers

Proposal for DCL

- Packages likely to be consumed as one or multiple servings:
  - Dual-column labeling presenting nutrition information per serving and per container would generally be required for products in packages that contain at least 200% of the RACC and up to and including 400%
  - Intended for products that can be consumed as one serving or as multiple servings

Proposal for DCL (cont.)

- Packages likely to be consumed as one or multiple servings:
  - FDA proposed a cut off level of 400% of the RACC
    - Based on an analysis of NHANES food consumption data showing that the ratio intake at the 90th percentile to the RACC was 400% or less for almost all products
    - Data suggests that 90% of the reported consumption amount is 400% of the RACC or less for almost all product categories

Proposed Exempted Products

- Products that meet the requirement to use the tabular format § 101.9(j)(13)(ii)(A)(1) or the linear format § 101.9(j) (13) (ii)(A)(2)

- Products used primarily as ingredients (e.g., flour, sweeteners and shortenings etc.) and products traditionally used for multi-purposes (e.g., eggs, butter and margarine etc.)

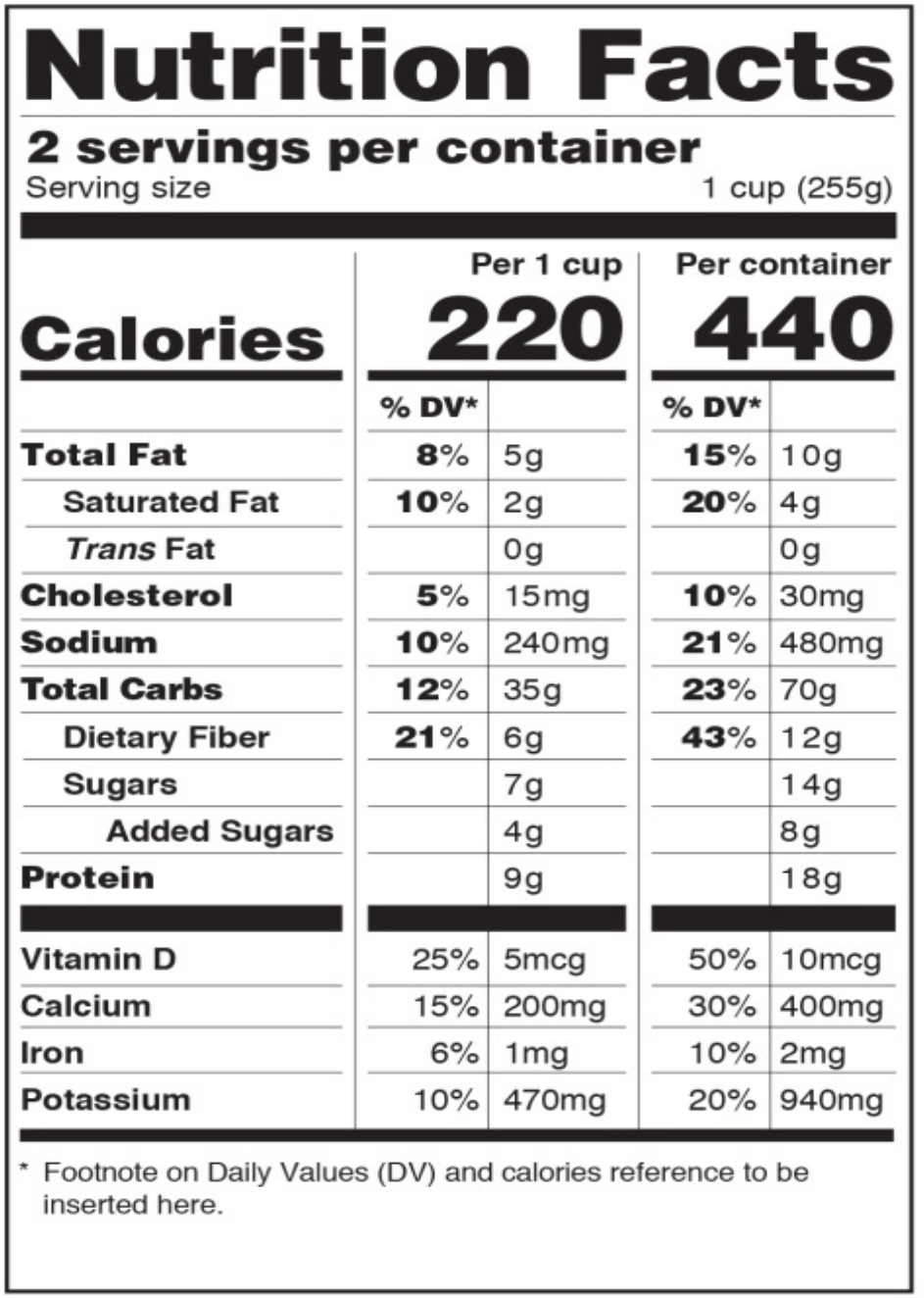
Proposed Exempted Products (cont.)

- Food products that require further preparation
- Food products that are commonly combined with other ingredients
  - Voluntarily contain more than one column of nutrition information
  - It is helpful to consumers to include nutrition information based on how the food in consumed

Proposal for Dual-Column Labeling

- FDA requested comments on other options for requiring certain nutrition information per serving and per container
  - Calories only
  - Calories, saturated fat and sodium
  - In these options, information listed per serving and per container would be beneath the serving size information and remaining nutrients would be listed on a per serving basis in a single column

Proposed Format for Dual Column Labeling



Nutrition Facts

2 servings per container

Serving size 1 cup (255g)

	Per 1 cup		Per container	
Calories	**220**		**440**	
	% DV*		**% DV***	
Total Fat	**8%**	5g	**15%**	10g
Saturated Fat	**10%**	2g	**20%**	4g
Trans Fat		0g		0g
Cholesterol	**5%**	15mg	**10%**	30mg
Sodium	**10%**	240mg	**21%**	480mg
Total Carbs	**12%**	35g	**23%**	70g
Dietary Fiber	**21%**	6g	**43%**	12g
Sugars		7g		14g
Added Sugars		4g		8g
Protein		9g		18g
Vitamin D	25%	5mcg	50%	10mcg
Calcium	15%	200mg	30%	400mg
Iron	6%	1mg	10%	2mg
Potassium	10%	470mg	20%	940mg

* Footnote on Daily Values (DV) and calories reference to be inserted here.

Current 1993 RACCs

- Based primarily on 1977–1978 and 1987–1988 nationwide food consumption surveys
  - Three statistical estimates from the survey data were used to determine the 1993 RACCs the mean, median and mode
  - Currently, there are 11 product categories for infants and children 1 to 3 years of age and 129 product categories for individuals 4 years or older
  - The RACCs are organized so that foods that have similar dietary usage and product characteristics are grouped together in product categories

Current 1993 RACCs (cont.)

- Other factors considered:
  - Consistency between product categories and within a product category
  - Dietary guidance documents
  - Canadian serving size
  - Commonly used serving size
  - Industry practice
  - Public comments

Scenarios for Updating, Modifying and Establishing the RACCs

- Update the 1993 RACCs
  - When intake data significantly changes from the 1993 RACCs
- Modify existing RACCs
  - When intake data does not significantly change from the 1993 RACCs but instead is based on requests from manufacturers and agency initiative
- Establish RACCs
  - For products that do not have RACCs

Data Sources Used

- What We Eat in America (WWEIA) National Health and Nutrition Examination Survey (NHANES)
  - Provides amounts of each food reported consumed in grams in the past 24-hours from each survey participant
  - Combined 2003-2004, 2005-2006, and 2007-2008 from the NHANES because starting in 2003, 2 days of consumption data have been available

Methods

- Analyze each product within product category
  - Calculate minimum sample size
  - Estimate the median
  - Determine if there was a significant increase or decrease in consumption levels from the 1993 RACCs

Minimum Sample Size Required

- FDA calculated the sample size needed under a simple random sample (SRS) to estimate the true value within a margin of error (or bound) of 20% of the 1993 RACC with 90% confidence
  - This SRS was then inflated (or reduced) by the design effect to obtain the minimum sample size required when taking into account the NHANES sample design and weighting

Updating the 1993 RACCs

- FDA ensured sample sizes were sufficient to be 90% confident of detecting if the median changed by *at least* 20% of the 1993 RACC
  - If products had sufficient sample sizes, the agency considered adjusting the 1993 RACC to the new median, if the lower confidence bound on the median is more than 125% of the 1993 RACC or the upper confidence bound on the median is less than 75% of the 1993 RACC

Other Factors Considered When Updating the 1993 RACCs

- Consistent RACCs for products in a product category and for products that have similar dietary usage, similar product characteristics, and are used interchangeably
- The reasonable consumption amount suggested in the Food and Nutrient Database for Dietary Studies

Proposed Updated RACCS for the General Food Supply

Food Product	Current RACC	Proposed RACC
Bakery products:		
Bagels	55 g	110 g
Toaster Pastries	55 g	110 g
Muffins (excluding English muffins)	55 g	110 g
Beverages:		
Carbonated and non-carbonated beverages, wine coolers, water	240 mL (8 fl oz.)	360 mL (12 fl oz.)
Coffee or tea, flavored and sweetened	240 mL (8 fl oz.)	360 mL (12 fl oz.)

Proposed Updated RACCs (cont.)

- Sugar
- All other candies
- Syrups not used as ingredients
- Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes.
- Avocado

Proposed Modified RACCs

Food Product	Current RACC	Proposed RACC
Dairy Products and Substitutes:		
Yogurt	225 g	170 g
Desserts:		
Ice cream, ice milk, frozen yogurt, sherbet, bulk	½ cup	1 cup
Ice cream, ice milk, frozen yogurt, sherbet, novelties	½ cup	1 cup
frozen flavored and sweetened ice, frozen fruit juices, bulk	85 g	1 cup
frozen flavored and sweetened ice, frozen fruit juices, novelties	85 g	½ cup

Proposed Modified RACCs (cont.)

- Fruits used primarily as ingredients
- Drink mixes (without alcohol); all types

Establishing Proposed New RACCs

- Factors considered:
  - USDA guidance document
  - Guidance for industry: A Food Labeling Guide
  - Industry practices (e.g., Mintel, Gladson databases)
  - Recipe calculation
  - National Nutrient Database for Standard Reference
  - Determine main dietary usage (e.g., Food Lover's Companion, allrecipes.com, etc.)

Proposed New RACCs

Food Product	Proposed RACC
Bakery products:	
Eggroll, Dumpling, Pot sticker, Wonton wrappers	20 g
Crepes	110 g
Scones and Crumpets	55 g
Mixed Dishes:	**Mixed Dishes:**
Appetizers, hors d'oeuvres, mini mixed dishes, e.g., mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, pot stickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins	85 g add 35 g for gravy or topping sauce

Proposed New RACCs (cont.)

- Seasoning oils and seasoning sauces and seasoning pastes
- After dinner confectionaries, liquid and powdered candies, fruit pastes and fruit chutney
- Several vegetable products
- Cocoa and carob powder
- Seafood substitutes

Impact of Changes in RACCs on Claims

- The agency recognizes that changes in RACCs will affect the eligibility of foods to bear nutrient content claims and health claims
  - Changes in the ability to make claims may be appropriate in light of American consumers changing eating patterns and changes in the amounts of foods customarily consumed
  - FDA invited comments related to its proposed RACC amendments

Submitting Comments

- Comment period has been extended until August 1, 2014
- www.regulations.gov
- Docket number: FDA-2004-N-0258